

Claims

- 5 1. A syringe type ampoule having a) a barrel with a front end and a rear end defining an axis therebetween, the barrel having substantially constant cross-section between the front end and the rear end, at least the front end ending in an opening, b) a sealer attached to the front end and sealing the opening, c) at least one piston movably and sealingly arranged within the barrel and d) a sleeve extending along at least a part of the barrel, the sleeve having a front part and a rear part, the front part being connected to the sealer, characterized in the improvement comprising that the barrel has a front end terminating in an edge surrounding the opening, the edge having an outer circumference substantially equal to the barrel outer
- 10 circumference.
2. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the barrel is substantially cylindrical and that the edge and barrel outer circumferences are substantially circular.
3. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the barrel cross-section is constant to a deviation of less than 2/mm, preferably less than 1 mm and most preferably less
- 15 than 0.5 mm, when measured as maximum to minimum outer diameter or generally between diametrical points on the outer circumference.
4. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sealer at least somewhere extends outside the outer diameter of the front end outer diameter and the barrel outer diameter.
- 20 5. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the barrel is of dual or multi chamber type incorporating at least one mixing arrangement between chambers.
6. The ampoule of claim 5, ^{wherein} ~~characterized in that~~ the mixing arrangement is a non-sealing section for the piston distributed substantially around the barrel circumference.
7. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the barrel has a rear end
- 25 terminating in an rear edge surrounding a rear opening, the rear edge having an outer circumference substantially equal to the barrel outer circumference.
8. The ampoule of claim 1 or 7, ^{wherein} ~~characterized in that~~ the edge is rounded.
9. The ampoule of claim 1 or 7, ^{wherein} ~~characterized in that~~ substantially all edge material is kept within the barrel external circumference.
- 30 10. The ampoule of claim 1 or 7, ^{wherein} ~~characterized in that~~ substantially all edge material is kept outside the barrel internal circumference.

11. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sealer has a part penetrating into the opening and having radial contact with the barrel interior surface.

12. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sealer has a flange part extension larger than the barrel circumference at the opening and/or larger than the barrel largest circumference.

13. The ampoule of claim 12, ^{wherein} ~~characterized in that~~ the extension is at least 0.05 mm, preferably at least 0,1 mm and most preferably at least 0,2 mm larger but smaller than 10 mm, preferably smaller than 5 mm and most preferably smaller than 2 mm.

14. The ampoule of claim 12, ^{wherein} ~~characterized in that~~ the flange has said extension around substantially its entire circumference.

15. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sealer is resilient.

16. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sleeve is attached to the barrel.

17. The ampoule of claim 16, ^{wherein} ~~characterized in that~~ the attachment is made to the rear part of the barrel.

18. The ampoule of claim 16, ^{wherein} ~~characterized in that~~ the attachment comprises at least one structure extending radially inwards behind barrel rear end.

19. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sleeve front part is connected to the sealer by at least one structure extending radially inwards in front of a sealer part.

20. The ampoule of claim 1, ^{wherein} ~~characterized in that~~ the sleeve comprises auxiliary structures, such as structures selected from the group consisting of fastening structures, guiding structures, plunger and fingergrasp structures, dosing mechanism structures, needle attachment structures or combinations thereof.

21. A process for the manufacture of a prefilled syringe type ampoule having a) a barrel with a front end and a rear end defining an axis therebetween, the barrel having substantially constant cross-section between the front end and the rear end, at least the front end ending in an opening, b) a sealer attached to the front end and sealing the opening, c) at least one piston movably and sealingly arranged within the barrel and d) a sleeve extending along at

least a part of the barrel, the sleeve having a front part and a rear part, the front part being connected to the sealer, ^{wherein} ~~characterized in that~~ the process comprises the steps of

inserting the piston through the front end opening to a distance from the opening into a sealing engagement with the barrel interior to form a chamber between the piston and the opening,

filling material into the chamber and

sealing the opening with the sealer.

22. The process of claim 21, ~~characterized in that~~ ^{wherein} a lyophilizing step is performed before the sealing step.

23. The process of claim 21, ~~characterized in that~~ ^{wherein} the sealing step includes the step of inserting a sealer part into the opening and contacting the part with the opening interior surface.

24. The process of claim 21 ~~or 23, characterized in~~ ^{wherein further comprising} connecting the sleeve to the sealer after the sealing step.

25. The process of claim 24, ~~characterized in~~ ^{further comprising} the step of securing the sleeve to the barrel rear end.

26. The process of claim 21, ~~characterized in~~ ^{further comprising} the step of inserting a second piston through the rear opening of the barrel.

27. The process of claim 21, ~~characterized in~~ ^{further comprising} the step of performing a filling operation through the rear opening before inserting the second piston.

28. ~~A prefilled syringe type ampoule manufactured according to the process of any one of claims 21 to 27.~~

29. A carrier/ampoule unit, for use in manufacture of prefilled ampoules, the unit comprising i) at least one ampoule and ii) a carrier having one or several seats for an ampoule, the seat providing a channel for axial insertion but radial retention of the ampoule, the ampoule comprising a) a container part with a front or upper end and a rear or lower end defining the ampoule axis therebetween, defining the radial directions perpendicular to the axis and defining an ampoule height and b) an opening to the container part at least at the front end, ~~characterized in the improvement comprising~~

that the channel is formed as a cavity,

that the cavity walls has at least the same height along the ampoule axis as the am-

poule height and

that the cavity walls are substantially continuous around said axis and along said height.

30. The unit of claim 29, characterized in that the ampoule container part is one from a group consisting of a tube, a vessel, a bag, a vial, a capsule, a carpoule, a syringe barrel and combinations thereof.

31. The unit of claim 30, characterized in that the container part is at least
5 partly symmetrical with constant cross-section around a symmetry axis.

32. The unit of claim 31, characterized in that the container part is tube-shaped.

33. The unit of claim 29, characterized in that the ampoule comprises a syringe barrel having a front opening and a rear opening.

10 34. The unit of claim 33, characterized in that the ampoule is substantially cylindrical.

35. The unit of claim 33, characterized in that the barrel is a dual or multi chamber type having at least one valve or by-pass arrangement.

15 36. The unit of claim 29, characterized in that the cavity is formed as a bore in a carrier body part, preferably substantially monolithic body part.

37. The unit of claim 29, characterized in that the channel width is about the same as ampoule largest width.

38. The unit of claim 29, characterized in that channel cross-section profile is about congruent with ampoule cross-section profile.

20 39. The unit of claim 29, characterized in that the channel has a length at least corresponding to ampoule length.

40. The unit of claim 39, characterized in that the channel is longer than the ampoule length.

25 41. The unit of claim 40, characterized in that the unit has a sealer arranged in the channel at the ampoule front end.

42. The unit of claim 41, characterized in that the sealer is frictionally held in the channel.

43. The unit of claim 29, characterized in that the seat comprises at least one lock attached to the carrier and able to restrict ampoule axial movement.

30 44. The unit of claim 43, characterized in that the lock has a surface extending into the channel at ampoule front and/or rear end.

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46. The unit of claim 45, characterized in that the surface only partially covers the ampoule end surface.

48. The unit of claim 47, characterized in that the locking surface comprises at least one bar or band spanning over more than one channel.

50. The unit of claim 43, characterized in that the seat comprises two locks with a separation at least equal to ampoule height.

51. The unit of claim 50, characterized in that the separation is larger than the ampoule height.

15 52. The unit of claim 51, characterized in that the ampoule and a sealer are arranged between the locks.

53. The unit of claim 29, characterized in that it comprises a tool arranged axially movable in relation to at least one channel and having a part able to enter the channel.

54. The unit of claim 53, characterized in that the tool is arranged at least at
20 the carrier upper end.

55. The unit of claim 53, characterized in that the tool is used as lock.

56. The unit of claim 53, characterized in that the tool have several parts able to enter several channels at the axial movement.

57. The unit of claim 53, characterized in that the carrier has guiding structures for the tool axial movement.

58. The unit of claim 57, characterized in that each channel is provided with individual guiding structures.

59. The unit of claim 57, characterized in that the guiding structures comprises a stop surface for the tool axial movement towards the channel.

30 60. The unit of claim 57, characterized in that the guiding structures com-
prises recesses in the carrier body.

61. The unit of claim 60, characterized in that

72. A carrier/ampoule unit, for use in manufacture of prefilled ampoules, the unit comprising i) at least one ampoule and ii) a carrier having one or several seats for an ampoule, the seat providing a channel for axial insertion but radial retention of the ampoule, the ampoule comprising a) a container part with a front or upper end and a rear or lower end defining

a lower lock surface attached to the channel and extending at least partially into the

an upper lock surface attached to the channel and extending at least partially into the channel,

10 at least one of the lower lock and the upper lock being releasably attached to the chan-
nel.

74. The unit of claim 72, characterized in any characteristic of claims 29 to

75. A carrier/ampoule unit, for use in manufacture of prefilled ampoules, the unit comprising i) at least one ampoule and ii) a carrier having one or several seats for an ampoule, the seat providing a channel for axial insertion but radial retention of the ampoule, the ampoule comprising a) a container part with a front or upper end and a rear or lower end defining the ampoule axis therebetween, defining the radial directions perpendicular to the axis and defining an ampoule height and b) an opening to the container part at least at the front end, characterized in the improvement comprising

a lower lock surface attached to each channel and extending at least partially into the

an upper lock surface attached to each channel and extending at least partially into the channel,

30 / guiding structures for at least the releasable lock arranged on the carrier at each chan-
nel.

76. The unit of claim 75, characterized in that at least the releasable lock is axially movable in relation to the channel.

77. The unit of claim 76, characterized in that the guiding structures comprising at least a stop surface limiting movement of the movable upper lock or lower lock towards
5 the channel.

78. The unit of claim 75, characterized in any of the characteristics of claims 29 to 63.

79. A method for the manufacture of prefilled ampoules by use of a carrier/ampoule unit, the unit comprising i) at least one ampoule and ii) a carrier having one or several seats
10 for an ampoule, the seat providing a channel for axial insertion but radial retention of the ampoule, the ampoule comprising a) a container part with a front or upper end and a rear or lower end defining the ampoule axis therebetween, defining the radial directions perpendicular to the axis and defining an ampoule height and b) an opening to the container part at least at the front end, ~~characterized in the steps of~~
the method comprising

15 inserting an ampoule in a channel,
filling material into the ampoule
sealing the ampoule opening with a sealer and
removing the ampoule from the channel.

80. The method of claim 79, characterized in the steps of inserting the am-
20 poule through a first end of the channel and performing through the same end of the channel an additional operation selected from the group consisting of inserting a piston into the ampoule container, filling a substance into the ampoule container, evaporating a component from the container, inserting a sealer into the channel, removing the ampoule from the channel and combinations of these steps.

25 81. The method of claim 80, characterized in the step of keeping the first end upright under the inserting and filling steps.

82. The method of claim 80, characterized in that the first end is the upper carrier end.

83. The method of claim 80, characterized in the evaporating step comprises
30 a lyophilizing step.

84. The method of claim 80, characterized in the step of performing from a second end of the channel an additional step selected from said group.

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85. The method of claim 84, characterized in the steps of turning the carrier upside down before performing the additional step.

86. The method of claim 79, characterized in performing between the ampoule interior and the carrier exterior an exchange step selected from the group consisting of a
5 gas exchange, a heat exchange, a pressure exchange and combinations thereof.

87. The method of claim 86, characterized in that the exchange step comprises a sterilization and/or a lyophilization step.

88. The method of claim 79, characterized in that the ampoule has a front opening and a rear opening and the step of passing a gas through the ampoule.

10 89. The method of claim 87, characterized in that the gas is a hot sterilizing gas.

90. The method of claim 79, characterized in the step of inserting a sealer in the channel into a rest position in a non-sealing relationship to the ampoule opening.

15 91. The method of claim 90, characterized in the step of performing a lyophilization after sealer insertion.

92. The method of claim 90, characterized in the step of moving the sealer in the channel from the rest position into a sealing engagement with the ampoule opening.

93. The method of claim 90, characterized in the step of holding the sealer in the rest position by friction between the sealer and the channel interior wall.

20 94. The method of claim 92, characterized in the step of securing the sealer with a capping.

95. The method of claim 94, characterized in the step of removing the ampoule from the carrier before the securing step.

96. An ampoule manufactured by the method of any of claims 79 to 95.

25 97. An ampoule having a barrel with a front end and a rear end defining an axis therebetween, the barrel having substantially constant cross-section between the front end and the rear end, at least the front end ending in an opening with a rounded edge, ^{wherein} ~~characterized in that~~ substantially all edge material is kept within the barrel external circumference and/or outside the barrel internal circumference, the circumference relating to the opening
30 barrel part close to the edge.

^{wherein} ~~characterized in that~~ 98. The ampoule of claim 97, characterized in that the rear barrel end has a rear opening with a rounded edge having the material distribution stated.

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A 99. The ampoule of claim 97, ^{wherein} ~~characterized in that~~ at least one opening is equipped with a sealer.

A 100. The ampoule of claim 97, ^{wherein} ~~characterized in that~~ the barrel comprises one of a by-pass arrangement, a piston or combinations thereof.

5 101. A method for manufacture of an ampoule having a barrel with a front end and a rear end defining an axis therebetween, at least the front end ending in an opening with a rounded edge with substantially all edge material is kept within the barrel external circumference and/or outside the barrel internal circumference, the circumference relating to the opening barrel part close to the edge, ^{the method comprising} ~~characterized in~~ the steps of heating a blank barrel
10 tube material around the circumference and separating the parts by axial pulling while the heated circumference is still hot.

A 102. The method of claim 101, ^{wherein} ~~characterized in~~ that the heating is made by laser.

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